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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,508	07/10/2000	Wei-Wu He	PF140P1D1	1213

22195 7590 08/13/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/13/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,508

Applicant(s)

HE ET AL.

Examiner

Gabri le E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002 and 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41, 43-68, 70-95, 97-122, 124-149, 151-176 and 178-181 is/are pending in the application.
- 4a) Of the above claim(s) 47, 74, 101, 128, 155 and 182 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 21-41,43-46,48-68,70-73,75-95,97-100,102-122,124-127,129-149,151-154,156-176 and 178-181.

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DETAILED ACTION

The amendment of 2/2002 is acknowledged. Claims 10-11, 1, 20, 42, 69, 96, 123, 150 and 177 have been cancelled. Claims currently pending are 21-41, 43-46, 48-68, 70-73, 75-95, 97-100, 102-122, 124-128, 130-149 151-154, 156-176 and 178-181.

Election/Restrictions

Applicant's election of Group I in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 47, 74, 101, 128, 155 and 182 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

The drawings have been approved by the draftsman.

Specification

The disclosure is objected to because of the following informalities:

This application does not fully comply with 37 C.F.R. 1.821-1.825 as several sequences do not appear to have corresponding SEQ ID Nos. For example, the pentapeptide QACRG appears in several locations, including page 2, line 9,

. Appropriate correction is required.

Information Disclosure Statement

References AA and AB have not been considered as no copies have been provide;
further, they are not published patent material.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 26-41, 43-46, 48, 53-68, 70-73, 75, 80-95, 97-100, 102, 107-122, 124-127, 129, 134-149, 150-154, 156, 161-176, 178-181 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel microorganisms specifically deposited at the ATCC. Since the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the microorganisms. It is noted that applicants have deposited the organisms but there is no indication in the specification as to public availability. As the deposit has been made under the terms of the Budapest Treaty (p 9, lines 14-17), then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating

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that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Claims 21, 30-41, 43-46, 48-68, 70-73, 75-95, 97-100, 102, 111-122, 124-127, 129-149, 151-154, 156-176, and 178-181 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides encoding human ICE-LAP 3 and 4 of SEQ ID No. 2 and 4, and the ICE-LAP 3 and 4 produced by the human cDNA clones in the deposited cell lines, does not reasonably provide enablement for nucleotides with e.g., 95% identity to the above or for fragments of these polynucleotides. . A The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification is directed toward the human protein and does not address mammalian homologs. The ICE protease family has become a subject of intense investigation and new members of this family are continually being added (see Henkart). . The specification provides no mutants and no guidance as to where the mutations should occur. The specification compares ICE-LAP 3 and 4 with ICE and ced-3 (figure 3), but does not show what features are unique to identity of a molecular variant as encoding ICE-LAP-3 or 4. There is no predictability as to which residues may be substituted so that the molecule can be identified as encoding either ICE-LAP 3 or 4, i.e., what distinguishes these from other members of the gene family. How is one to determine whether a given gene with 95% identity e.g., is a derivative of either ICE-LAP 3 or 4 or another member of the ICE family?

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With respect to fragments of the genes, the specification provides no guidance regarding which fragments are useful for any purpose. While one can randomly make fragments, there is no predictability as to how they may be used. Some may be useful for raising specific antisera, but which ones should be chosen? Which are specific ICE_LAP 3 and/or 4 probes? It would thus require experimentation to determine which fragments should be obtained..

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 28, 32-41, 43-46, 48, 55, 59-68, 70-73, 75, 82, 86-95, 97-100, 102, 109, 113-122, 124-127, 129, 136, 140-149, 151-154, 156, 163, 167-176 and 177-181 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Part (g) of each of claims 21, 48, 75, 102, 129 and 156 specifies a mature portion of the polypeptide. It is unclear what is meant by this term- is a fragment of the mature polypeptide intended, or the portion of the encoded polypeptide that becomes the mature protein?

Claims 28, 32-41, 43-46, 55, 59-68, 70-73, 82, 86-95, 97-100, 109, 113-122, 124-127, 136, 140-149, 151-154, 163, 167-176 and 177-181 are included in this rejection as they depend from the claims listed in the immediately preceding paragraph and do not clarify the ambiguity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-41, 43-46, 48-68, 70-73, 75-95, 97-100, 102-122, 124-126, 128-149, 151-154, 156-176 and 178-181 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43, 44 and 46 of copending Application No. 08/334251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite the polynucleotide encodes the peptides of either SEQ ID NO:3 or SEQ ID NO:4 while those of the copending application recite polynucleotides of SEQ ID NO:1 or 3 ; however, SEQ ID NO:1 and 3 encode polypeptides of SEQ ID NO:2 and 4, respectively. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

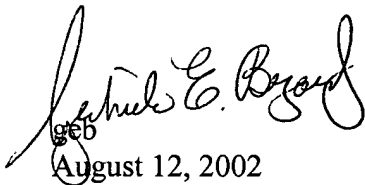
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15-12:15 M, 8:15-1:15 Tu-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.


geb
August 12, 2002

Gabriele E. BUGAISKY
Primary Examiner
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